K101217

JUN 23 2010

RehaMed International, LLC
522 West Mowry Drive
Homestead, FL 33030

305-586-7779

510(k) Summary
Prepared 4/28/10

Submitted By	RehaMed International, LLC 522 West Mowry Drive Homestead, FL 33030 Phone: 305-586-7779
Contact Person	John Caden President 144 Severino Drive Islamorada, FL 33036 Phone: 305-586-7779 eMail: johnjcaden@gmail.com
Trade Name of Device	MAC-Mobile Aquatic Chair
Common Name of Device	Wheelchair, Mechanical
Proposed Classification of New Device	Class 1 21 CFR section 890.3850 Wheelchair, Mechanical
Panel	Physical Medicine Prosthetic Devices Subpart D 890
Product Code	IOR
Existing Classification of Predicate Device	Class 1 21 CFR section 890.3850 Wheelchair, Mechanical
Legally Marketed Predicate Device for Claimed Equivalence	Stainless Steel Aquatic Wheelchair Marketed by D.B. Perks & Associates Under 510(k) K031910 Granted July 25, 2003

Intended Use of the Device	This wheelchair provides mobility to non-ambulatory persons. The device is used primarily for transferring into a swimming pool via a ramp
Target Populations	Any non-ambulatory person who wishes to gain access to a swimming pool via a ramp.
Device Comparison	The device is substantially equivalent to the predicate device listed above. Both products have the same technological characteristics and indications for use. Both products are designed to be used in a swimming pool environment. Appendix 1 contains product information of the predicate device.
Device Description	The MAC-Mobile Aquatic Chair features a rigid frame design and is suitable to provide mobility both indoors and in wet conditions. Primarily designed to assist non-ambulatory users to gain entry to a swimming pool via a ramp, the Aquatic Wheelchair features anti-tip wheels that are built into the design. The MAC-Mobile Aquatic Chair is fabricated from stainless steel that is coated with a tough powder coated finish. The wheels and casters are made from a water friendly plastic material. The rigid plastic seat is specifically designed for use in an aquatic environment. The entire product can be submersed into pool water with no harmful effects. The User's Manual provides information on warnings, maintenance, and operating instructions. Photographs of the product are contained in Appendix 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

RehaMed International, LLS
% Mr. John Caden
President
522 West Mowry Drive
Homestead, Florida 33030

JUN 23 2010

Re: K101217
Trade/Device Name: MAC-Mobile Aquatic Chair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: April 28, 2010
Received: April 30, 2010

Dear Mr. Caden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101217
Device Name: MAC-Mobile Aquatic Chair
Indications For Use:

This wheelchair provides mobility to non-ambulatory persons. The device is used primarily for transferring individuals into a swimming pool via a ramp. This device is designed to be a typical manual wheelchair for use in an aquatic center setting.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101217